REMARKS

The Official Action dated August 23, 2005 has been carefully considered. Accordingly, the following remarks are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 9, 23 and 26 are amended to further clarify the steps of the methods for serological identification and diagnosis. Support for these amendments may be found throughout the specification. Claim 10 is amended for a matter of form. Claim 16 is amended to recite a selected embodiment. Claim 29 is added and support for claim 25 may be found in the specification, for example in the paragraph bridging pages 3 and 4 and in the detailed examples set forth at pages 4-7 of the application. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claims 9-28 were rejected under 35 U.S.C. §102(b) as being anticipated by Duro et al, *FEBS Letters*, 399 (1996), 295-298. The Examiner asserted that Duro et al perform the claimed method step and that the preambles of the present claims are not actual method steps but only intended uses of the method and therefore are inherent in Duro et al. The Examiner further asserted that Duro et al also teach that previous to their disclosed methods, the Pj allergen was know to have at least nine allergens having different molecular weights and in order to plan a diagnostic and therapeutic approach to allergic reaction, a preliminary step is to purify and characterize, i.e., serologically identify with improved accuracy, each major allergen by cloning the allergen and testing its immunoreactivity in blood from patients with Pj reactivity.

However, Applicants submit that the methods defined by claims 9-21 and 23-29 are not anticipated by and are patentably distinguishable from the teachings of Duro et al. Accordingly, this rejection is traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 9, the invention is directed to a method for serologically identifying with improved accuracy the actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes. The method comprises contacting serum with a pure allergen component of limited or no cross-reactivity, determining, in the serum, the presence of IgE binding to the pure allergen component, and identifying the source from which said pure allergen component is derived as the actual sensitizing allergen source if the serum contains IgE binding to the pure allergen component.

According to claim 23, the invention is directed to a method for serologically identifying with improved accuracy an individual's sensitivity to *Parietaria* pollen, comprising contacting a serum sample from the individual with a pure allergen component of Par j 1 or Par j 2, determining, in the serum, the presence of IgE binding to the pure allergen component, and identifying the individual as sensitive to *Parietaria* pollen if the serum contains IgE binding to the pure allergen component.

Finally, as defined by claim 26, the invention is directed to a method for serological diagnosis for an individual of an actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes with improved accuracy. The method for serological diagnosis comprises contacting a serum sample from the individual for which diagnosis is desired with a pure allergen component of limited or no cross-reactivity, determining, in the serum, the presence of IgE binding to the said pure allergen component, and identifying the source from which the pure allergen component is derived as the actual sensitizing allergen source if the serum contains IgE binding to the pure allergen component.

Thus, the present methods are for accurately identifying the actual sensitizing allergen source among a variety of allergens. One skilled in the art will appreciate therefore that the

present methods are not for generally diagnosing allergy, as the individual has probably already been generally diagnosed with allergy. Rather, the present methods are for identifying to which particular allergen the individual is allergic, which can then be used by a physician in deciding a therapeutic strategy.

The methods of the present invention are based on the surprising discovery that it is possible to identify the actual sensitizing allergen among a variety of possible allergen sources containing cross-reactive proteins or epitopes. This is done by detecting that a pure allergen component with limited or no cross-reactivity only binds to patients that are primarily sensitized to the allergen source from which the component is derived. For example, in the specific embodiment involving *Parietaria* pollen exemplified in the application, Applicants have determined that *Parietaria* pollen extract binds IgE from individuals not exposed to *Parietaria* pollen, while pure rPar j 2 does not bind to IgE from such individuals. However, rPar j 2 does bind IgE from most allergic individuals who are primarily sensitized to *Parietaria* pollen. Thus, Applicants have developed the present methods for specific identification of such an actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes by contacting serum with a pure allergen component of limited or no cross-reactivity. The ability to make such an accurate identification from a serum sample is clearly advantageous in allergy diagnosis and in allergy treatment.

Duro et al disclose the cloning and characterization of the allergen Par j 2.0101. While the authors mention that in a diagnostic/therapeutic approach, a preliminary step is to purify and characterize each major allergen, this is only a general statement relating to all allergens and all diagnostic and therapeutic strategies. Applicants find no teaching or suggestion regarding any specific diagnostic method or approach. Particularly, Applicants find no teaching or suggestion by Duro et al regarding a method for accurately identifying an

actual sensitizing allergen among a variety of possible allergens containing cross-reactive proteins or epitopes as required by claims 9, 23 and 26.

The Examiner asserted in the Official Action that the preambles of the present claims add no additional limitations to the claims since the same product was used in the same method steps for identifying allergens for patients. First, it is well settled that a preamble generally limits the claimed invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781 (Fed. Cir. 2002). Thus, if the preamble helps to determine the scope of the patent claim, then it is construed as part of the claimed invention; particularly, when the claim drafter chooses to use both the preamble and the body to define the subject matter of the claimed invention, the invention so defined, and not some other, is the one the patent protects. *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816 (Fed. Cir. 1995). Additionally, when limitations in the body of the claim rely upon and derive antecedent basis from the preamble, then the preamble may act as a necessary component of the claimed invention. *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339, 66 USPQ2d 1271 (Fed. Cir. 2003). Thus, the Examiner may not disregard the preamble of claims 9, 23 or 26.

Moreover, claims 9, 23 and 26 recite additional steps which further illustrate the distinctions between the claimed invention and the teachings of Duro et al. Particularly, the method of claim 9 requires, in addition to contacting serum with a pure allergen component of limited or no cross-reactivity, the steps of determining the presence of IgE binding to the pure allergen component in the serum and, if the serum contains IgE binding to the pure allergen component, identifying the source from which the pure allergen component is derived as the actual sensitizing allergen source. In the more specific embodiment of claim 23, the setp of contacting a serum sample from the individual with a pure component of Par j

1 or Par j 2 is followed by similar determination and identification steps. Further, claim 26 includes not only the step of contacting a serum sample from the individual for which diagnosis is desired with a pure allergen component of limited or no cross-reactivity, but the additional steps of determining the presence of IgE binding to the pure allergen component in the serum and, if the serum contains IgE binding to the pure allergen component, identifying the source from which the pure allergen component is derived as the actual sensitizing allergen source.

Duro et al provide no teaching, suggestion or recognition of such method steps for serologically identifying the actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes, as required by claim 9, for serologically identifying with improved accuracy an individual sensitivity to *Parietaria* pollen, as recited in claim 23, or for serological diagnosis for an individual of an actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes with improved accuracy. Particularly, Duro et al do not identify an individual allergen sensitivity. Rather, the serum samples described at page 297 of Duro et al were from patients previously identified as allergic to *P. judaica* pollen or not allergic to Pj pollen.

In contrast, according to the present methods, an individual who may, for example, have been generally diagnosed as exhibiting allergy to weed pollen, for which many cross-reactive proteins or epitomes exist, may be provided with serological identification or diagnosis with improved accuracy of the actual sensitizing allergen source. Duro et al disclose one experiment concerning the cross-reactivity of Par j 2, and they conclude that Par j 1 and Par j 2 are not cross-reactive and do not share common IgE epitopes (page 297, right column). However, Duro et al do not draw any conclusion that this finding, or any other teaching in their publication, may be relevant to diagnostics. In contrast, the present methods

are for improved identification of diagnosis among a variety of possible allergen sources containing cross-reactive proteins or epitopes. Accordingly, Duro et al provide no teaching or suggestion of the present methods.

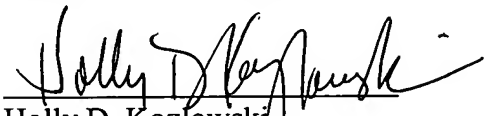
Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference. *In re Robertson*, 169 F.3d 743, 745, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Duro et al to teach a method for serologically identifying the actual sensitizing allergen source among a variety of possible allergen sources containing cross-reactive proteins or epitopes, Duro et al do not anticipate the methods of claims 9, 23, 26, or claims 10-21, 24, 25 or 27-19 dependent thereon.

In fact, dependent claim 10 further demonstrates the deficiencies in the teachings of Duro et al. Claim 10 recites the method according to claim 9 for selection of treatment of a disorder involving extract, proteins or peptides derived from said actual sensitizing allergen source. One skilled in the art will recognize the significance of the present methods in the ability to select a safe and effective treatment of this type. Not only do Duro et al fail to teach the method of claim 9, 23 or 26, Applicants find no teaching by Duro et al regarding the use of such a method for selection of treatment involving extract, proteins or peptides derived from said actual sensitizing allergen source. Duro et al's brief reference to plan a diagnostic and therapeutic approach to allergic reaction, does not teach or suggest methods as presently claimed.

Accordingly, the methods defined by claims 9-21 and 23-29 are not anticipated by and are patentable over Duro et al, whereby the rejection under 35 U.S.C. §102 has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejection under 35 U.S.C. §102, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,



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